



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Buechler et al.

Title: MARKERS FOR DIFFERENTIAL
DIAGNOSIS AND METHODS OF
USE THEREOF

Appl. No.: 10/603,891

Filing Date: 06/24/2003

Examiner: Unknown

Art Unit:

CERTIFICATE OF MAILING

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10/21/03
(Date of Deposit)

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 10/330,696, filed 12/27/2002. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

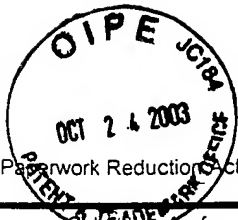
Respectfully submitted,

Date 10/21/03

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By Barry Wilson

Barry S. Wilson
Attorney for Applicant
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PTO/SB/08 (08-00)

Approve use through 10/31/2002. OMB 0651-0031

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Substitute for form 1449B/PTO
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: April 14, 2003

(use as many sheets as necessary)

Sheet 1 of 27

Complete if Known

Application Number	10/330,696
Filing Date	12/23/2002
First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	071949-5602

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	6,156,521		Buechler et al.	12/05/00	
	A2	6,147,688		Clair	11/14/00	
	A3	6,143,576		Buechler	11/07/00	
	A4	6,113,855		Buechler	09/05/00	
	A5	6,019,944		Buechler	02/01/00	
	A6	5,985,579		Buechler et al.	11/16/99	
	A7	5,955,377		Maul et al.	09/21/99	
	A8	5,947,124		Buechler et al.	09/07/99	
	A9	5,939,272		Buechler et al.	08/17/99	
	A10	5,922,615		Nowakowski et al.	07/13/99	
	A11	5,885,527		Buechler	03/23/99	
	A12	5,851,776		Valkirs	12/22/98	
	A13	5,843,690		Gargan	12/01/98	
	A14	5,824,799		Buechler et al.	10/20/98	
	A15	5,795,725		Buechler et al.	08/18/98	
	A16	5,679,526		Buechler et al.	10/21/97	
	A17	5,631,171		Sandstrom et al.	05/20/97	
	A18	5,525,524		Buechler et al.	06/11/96	
	A19	5,480,792		Buechler et al.	01/02/96	
	A20	5,453,359		Gargan	09/26/95	

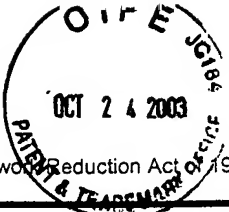
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		Examiner Name	Unassigned
Sheet 2 of 27	Attorney Docket Number	071949-5602	

FOREIGN PATENT DOCUMENTS								
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	B1	EPO	999447A1					
	B2	WO	01/16599 A1					

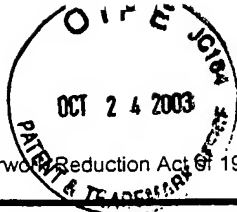
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	C1	Aggarwal et al., "Evaluation of serum lipid profile and cardiac enzyme changes in cerebrovascular accidents," <i>JIMA</i> , 93:331-332 (1995).	
	C2	Akiyama et al., "Changes in serum concentrations of matrix metalloproteinases, tissue inhibitors of metallo proteinases and Type IV collagen in patients with various types of glomerulonephritis," <i>Res. Commun. In Mol. Path. and Pharm.</i> , 95(2): 115-128 (1997).	
	C3	Albrechtsen, M. and Bock, E. J., "Quantification of Glial Fibrillary Acidic Protein (GFAP) in Human Body Fluids by means of ELISA Employing a Monoclonal Antibody," <i>Neuroimmunol.</i> 8:301-309 (1985).	
	C4	Amaro, A. et al., "Plasma leukocyte elastase concentration in angiographically diagnosed coronary artery disease," <i>Eur. Heart J.</i> 16:615-622 (1995).	
	C5	Ardissino, D. et al., "Tissue-factor antigen and activity in human coronary atherosclerotic plaques," <i>Lancet</i> 349:769-771 (1997).	
	C6	Asano, Y. et al., "Clinical Significance of surfactant protein D as a serum marker of evaluating pulmonary fibrosis in patients with systemic sclerosis," <i>Arthritis Rheum</i> 44(6):1363-9 (June 2001).	
	C7	Austgulen et al., "Increased maternal plasma levels of soluble adhesion molecules (ICAM-1, VCAM-1, E-selectin) in preeclampsia," <i>Eur. J. Obstet. Gynecol. Reprod. Biol.</i> , 71:53-58 (1997).	
	C8	Badr-elDin et al., "Eosinophil cationic protein as a serological marker of disease activity in childhood bronchial asthma," <i>East Mediterr. Health J.</i> 5:664-75 (1999).	
	C9	Baker, T. et al., "Serum metalloproteinases and their inhibitors: markers for malignant potential," <i>Br. J. Cancer</i> 70:506-512 (1994).	

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		Filing Date	12/23/2002		
		First Named Inventor	Kenneth F. Buechler		
		Group Art Unit	Unassigned		
		Examiner Name	Unassigned		
Sheet	3	of	27	Attorney Docket Number	071949-5602

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

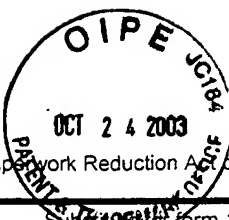
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	C10	Balogopalakrishna, C. <i>et al.</i> , "Modification of low density lipoproteins by erythrocytes and hemoglobin under hypoxic conditions, <i>Adv. Exp. Med. Biol.</i> 411:337-345 (1997).	
	C11	Bandoh <i>et al.</i> , "Sequential changes of KL-6 in sera of patients with interstitial pneumonia associated with polymyositis/dermatomyositis," <i>Ann. Rheum. Dis.</i> 59:257-62 (2000).	
	C12	Banks <i>et al.</i> , "Circulating intercellular adhesion molecule-1 (ICAM-1), E-selectin and vascular cell adhesion molecule-1 (VCAM-1) in human malignancies," <i>Br. J. Cancer</i> 68:122-124 (1993).	
	C13	Bates <i>et al.</i> , "Neurotrophin-3 promotes cell death induced in cerebral ischemia, oxygen-glucose deprivation, and oxidative stress: possible involvement of oxygen free radicals," <i>Neurobiology of Disease</i> 24-37 (2002).	
	C14	Bayes-Genis, A. <i>et al.</i> , "Elevated levels of plasmin- α 2 antiplasmin complexes in unstable angina," <i>Thromb. Haemost.</i> 81:865-68 (1999).	
	C15	Bazzan, M. <i>et al.</i> , "No evidence of platelet activation during atrial pacing in subjects with stable angina," <i>Cardiologia</i> 34:217-220 (1989).	
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	C17	Bertinchant, J.P. <i>et al.</i> , "Release kinetics of serum cardiac troponin I in ischemic myocardial injury," <i>Clin. Biochem.</i> 29:587-594 (1996).	
	C18	Bialik <i>et al.</i> , "Myocyte apoptosis during acute myocardial infarction in the mouse localizes to hypoxic regions but occurs independently of p53," <i>J. Clin. Invest.</i> 100(6): 1363-1372 (1997).	
	C19	Biasucci <i>et al.</i> , "Episodic activation of the coagulation system in unstable angina does not elicit an acute phase reaction," <i>Am. J. of Cardiol.</i> 77:85-87 (1996).	
	C20	Biasucci, L.M. <i>et al.</i> , "Temporal relation between ischemic episodes and activation of the coagulation system in unstable angina," <i>Circulation</i> 93:2121-2127 (1996).	
	C21	Biasucci <i>et al.</i> , "Elevated levels of interleukin-6 in unstable angina," <i>Circulation</i> 94:874-877 (1996).	
	C22	Biasucci <i>et al.</i> , "Increasing levels of interleukin (IL)-1Ra and IL-6 during the first 2 days of hospitalization in unstable angina are associated with increased risk of in-hospital coronary events," <i>Circulation</i> 99:2079-2084 (1999).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Date Submitted: April 14, 2003

(use as many sheets as necessary)

Sheet 4 of 27

Application Number	10/330,696
Filing Date	12/23/2002
First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	071949-5602

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C23	Bitsch et al., "A longitudinal prospective study of soluble adhesion molecules in acute stroke," <i>Stroke</i> , 29:2129-2135 (1998).	
	C24	Blankaert et al., "Constitutive release of metalloproteinase-9 (92-kd Type IV collagenase) by Kaposi's sarcoma cells," <i>J. Acquir. Immune Defic. Syndr. Hum. Retrovirol.</i> 18:203-209 (1998).	
	C25	Blann et al., "Soluble intercellular adhesion molecule-1, E-selectin, vascular cell adhesion molecule-1 and von Willebrand factor in stroke," <i>Blood Coagul. Fibrinolysis</i> 10:277-284 (1999).	
	C26	Blann, A.D. et al., "Evidence of platelet activation in hypertension," <i>Thromb. Haemost.</i> 77:1077-1080 (1997).	
	C27	Blann, A.D. et al., "Soluble P-selectin in atherosclerosis: a comparison with endothelial cell and platelet markers," <i>J. Hum. Hypertens.</i> 11:607-609 (1997).	
	C28	Bonfrer et al., "The luminescence immunoassay S-100: a sensitive test to measure circulating S-100B: its prognostic value in malignant melanoma," <i>Brit. Jour. Of Cancer</i> 77(12): 2210-2214 (1998).	
	C29	Bollensen et al., "Adenylate kinase enzyme activity in cases of brain infarction," <i>Acta Neurol. Scand.</i> 79:53-58 (1989).	
	C30	Bonomini, M. et al., "Serum levels of soluble adhesion molecules in chronic renal failure and dialysis patients," <i>Nephron</i> 79:399-407 (1998).	
	C31	Bonow, "New insights into the cardiac natriuretic peptides," <i>Circulation</i> 93:1946-1950 (1996).	
	C32	Bossnik et al., "Plasma levels of the chemokines monocyte chemotactic proteins-1 and -2 are elevated in human sepsis," <i>Blood</i> 86(10): 3841-3847 (1995).	
	C33	Bousquet et al., "Eosinophilic inflammation in asthma," <i>New Engl. J Med.</i> 323:1033-9 (1990).	
	C34	Bowen-Pope, D.F. et al., "Platelet-derived growth factor in vivo: levels, activity, and rate of clearance," <i>Blood</i> 64:458-469 (1984).	
	C35	Brooks and Ergul, "Identification of amino acid residues in the C-terminal tail of big endothelin-1 involved in processing to endothelin-1," <i>J. Mol. Endocrinol.</i> 21:307-15 (1998).	
	C36	Brown, D.L. et al., "Identification of 92-kd gelatinase in human coronary atherosclerotic lesions," <i>Circulation</i> 91:2125-2131 (1995).	

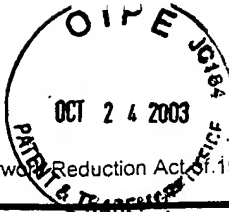
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Sheet 5 of 27		Attorney Docket Number	071949-5602

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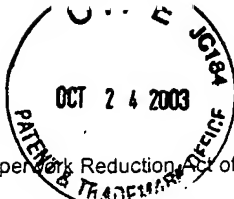
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	C37	Caligiuri et al., "Immune system activation follows inflammation in unstable angina: pathogenetic implications," <i>J.Am. Coll. Cardiol.</i> 32:1295-1304 (1998).	
	C38	Carlstedt et al., "Proinflammatory cytokines, measured in a mixed population on arrival in the emergency department, are related to mortality and severity of disease," <i>Journal of Internal Medicine</i> 242:361-365 (1997).	
	C39	Carraro, U. and Franceschi, C., "Apoptosis of skeletal and cardiac muscles and physical exercise," <i>Aging (Milano)</i> 9:19-34 (1997).	
	C40	Carter et al., "Platelet GP IIIa P1A and GP Ib variable number tandem repeat polymorphisms and markers of platelet activation in acute stroke," <i>Arterioscler. Thromb. Vasc.</i> 18:1124-1131 (1998).	
	C41	Carter et al., "Purification, cloning, expression and biological characterization of an interleukin-1 receptor antagonist protein," <i>Nature</i> 344:633-638 (1990).	
	C42	Carville, D.G. et al., "Thrombus precursor protein (TpP™): marker of thrombosis early in the pathogenesis of myocardial infarction," <i>Clin. Chem.</i> 42:1537-1541 (1996).	
	C43	Catto et al., "von Willebrand factor and factor VIII: C in acute cerebrovascular disease," <i>Thromb. Haemost.</i> 77:1104-8 (1997).	
	C44	Chong, B.H. et al., "Plasma P-selectin is increased in thrombotic consumptive platelet disorders," <i>Blood</i> 83:1535-1541 (1994).	
	C45	Colucciello, S.A., <i>EMR Texbook</i> , pp. 1-23 http://www.thrombosis-consult.com/articles/Texbook/54_pulmonary , printed 11/04/2002	
	C46	Cohen, A.M. et al., "Plasma clearance and tissue distribution of recombinant human platelet-derived growth factor (B-chain homodimer) in rats," <i>J. Surg. Res.</i> 49:447-452 (1990).	
	C47	Crouch, "Surfactant protein-D and pulmonary host defense," <i>Respir. Res.</i> 1: 93-108 (2000).	
	C48	Curzen et al., "Can C reactive protein or troponins T and I predict outcome in patients with intractable unstable angina?" <i>Heart</i> 80:23-27 (1998).	
	C49	D'Astou, M., "Diastolic Heart Failure," <i>Persp. In Cardiology</i> pp. 30-37 (May 2002).	
	C50	Dangas et al., "Correlation of serum lipoprotein(a) with the angiographic and clinical presentation of coronary artery disease," <i>Am. J. Cardiol.</i> 83:583-585 (1999).	

Examiner Signature	Date Considered
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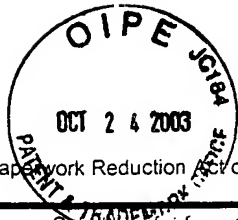
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	C51	Dao <i>et al.</i> , "Utility of B-Type Natriuretic Peptide in the Diagnosis of Congestive Heart Failure in an Urgent-Care Setting," <i>J. Am. Coll. Cardiol.</i> 37:379-85 (2001).	
	C52	Davi, G. <i>et al.</i> , "Increased levels of soluble P-selectin in hypercholesterolemic patients," <i>Circulation</i> 97:953-957 (1998).	
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		Examiner Name	Unassigned
Sheet	7 of 27	Attorney Docket Number	071949-5602

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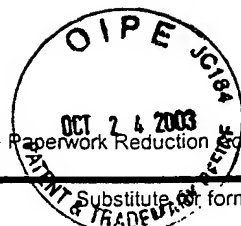
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	C65	Emsley et al., "Crystal structure of the von Willebrand factor A1 domain and implications for the binding of platelet glycoprotein Ib," <i>Journal of Biological Chemistry</i> 273(17): 10396-10401, (1998).	
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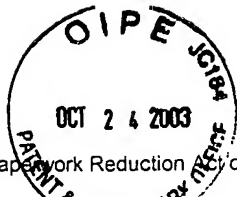
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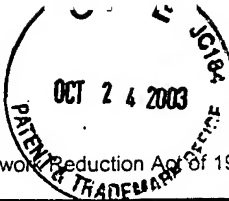
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	C103	Gurfinkel, E. <i>et al.</i> , Importance of thrombosis and thrombolysis in silent ischaemia: comparison of patients with acute myocardial infarction and unstable angina," <i>Br. Heart J.</i> 71:151-55 (1994).	
	C104	Hammer-Lercher <i>et al.</i> , "Head-to-head comparison of N-terminal pro-brain natriuretic peptide, brain natriuretic peptide and N-terminal pro-atrial natriuretic peptide in diagnosis left ventricular dysfunction," <i>Clin. Chim. Acta</i> 310(2):193-7 (2001).	
	C105	Hammerman, S.I. <i>et al.</i> , "Endothelial cell nitric oxide production in acute chest syndrome," <i>Am. J. Physiol.</i> 277:H1579-H1592 (1999).	
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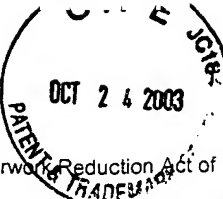
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	C116	Hoffmeister, H.M. <i>et al.</i> , "Correlation between coronary morphology and molecular markers of fibrinolysis in unstable angina pectoris," <i>Atherosclerosis</i> 144:151-157 (1999).	
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	C129	Jacque <i>et al.</i> , "Myelin basic protein in CSF and blood," <i>Arch. Neurol.</i> , 39: 557-560, 1982.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>April 14, 2003</u> (use as many sheets as necessary)		Application Number	10/330,696
		Filing Date	12/23/2002
		First Named Inventor	Kenneth F. Buechler
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 12 of 27	Attorney Docket Number	071949-5602	

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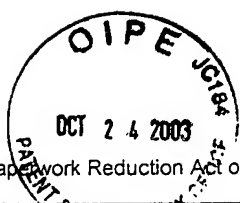
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	C130	James, T., "The variable morphological coexistence of apoptosis and necrosis in human myocardial infarction: significance for understanding its pathogenesis, clinical course, diagnosis and prognosis," <i>Coron. Artery Dis.</i> 9:291-307 (1998).	
	C131	Janoff, A., "Elastase in tissue injury," <i>Annu Rev Med</i> 36:207-216 (1985).	
	C132	Jensen et al., "Characterization of human brain S100 protein fraction: amino acid sequence of S100 β ," <i>J. Neurochem.</i> 45:700-705 (1985).	
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		Filing Date	12/23/2002
		First Named Inventor	Kenneth F. Buechler
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet	13	of	27
		Attorney Docket Number	071949-5602

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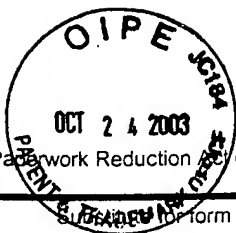
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	C143	Kato, K. <i>et al.</i> , "Immunoassay of human muscle enolase subunit in serum: a novel marker antigen for muscle diseases," <i>Clin. Chim. Acta</i> 131:75-85 (1983).	
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		Application Number	10/330,696
		Filing Date	12/23/2002
		First Named Inventor	Kenneth F. Buechler
		Group Art Unit	Unassigned
Examiner Name	Unassigned		
Attorney Docket Number	071949-5602		
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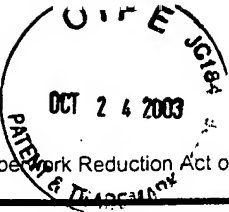
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	C157	Kosar, F. <i>et al.</i> , "Plasma leukocyte elastase concentration and coronary artery disease," <i>Angiology</i> 49:193-201 (1998).	
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	C167	Kuwasako <i>et al.</i> , "Increased plasma proadrenomedullin N-terminal 20 peptide in patients with essential hypertension," <i>Ann. Clin. Biochem.</i> 36:622-628 (1999).	
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		Filing Date	12/23/2002		
		First Named Inventor	Kenneth F. Buechler		
		Group Art Unit	Unassigned		
		Examiner Name	Unassigned		
Sheet	15	of	27	Attorney Docket Number	071949-5602

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	C169	Landi et al., "Hypercoagulability in acute stroke: Prognostic significance," <i>Neurol.</i> , 37:1667-1671 (1987).	
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	C171	Latini et al., "Cytokines in acute myocardial infarction: selective increase in circulating tumor necrosis factor, its soluble receptor, and interleukin-1 receptor antagonist," <i>J. Cardiovasc. Pharmacol.</i> , 23:1-6 (1994).	
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	C181	Liuzzo et al., "Plasma protein acute-phase response in unstable angina is not induced by ischemic injury," <i>Circulation</i> 94:2373-2380 (1996).	

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Date Submitted: April 14, 2003

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Sheet 16 of 27

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Application Number	10/330,696
Filing Date	12/23/2002
First Named Inventor	Kenneth F. Buechler
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	C182	Livrea, M.A. <i>et al.</i> , "Oxidative modification of low-density lipoprotein and atherogenetic risk in β -thalassemia," <i>Blood</i> 92:3936-3942 (1998).	
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	C185	MacManus, J.P. <i>et al.</i> , "Glycogen phosphorylase isoenzyme BB to diagnose ischaemic myocardial damage," <i>J. Cereb. Blood Flow Metab.</i> 19:502-510 (1999).	
	C186	Mahadevan, D. <i>et al.</i> , "Structural role of extracellular domain 1 of α -platelet-derived growth factor (PDGF) receptor for PDGF-AA and PDGF-BB binding," <i>J. Biol. Chem.</i> 270:27595-27600 (1995).	
	C187	Mair, J. <i>et al.</i> , "Early release of glycogen phosphorylase in patients with unstable angina and transient ST-T alterations," <i>Br. Heart J.</i> 72:125-127 (1994).	
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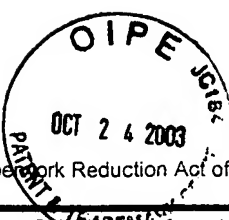
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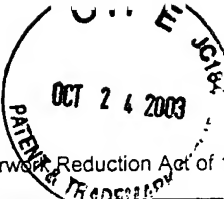
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	C196	Matsuda, H. <i>et al.</i> , "A sandwich enzyme immunoassay for human muscle-specific β -enolase and its application for the determination of skeletal muscle injury," <i>Forensic Sci. Int.</i> 99:197-208 (1999).	
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		Filing Date	12/23/2002
		First Named Inventor	Kenneth F. Buechler
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet	18 of 27	Attorney Docket Number	071949-5602

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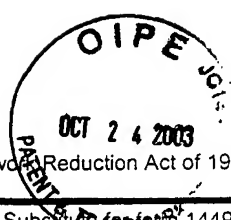
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		Filing Date	12/23/2002
		First Named Inventor	Kenneth F. Buechler
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 19 of 27	Attorney Docket Number	071949-5602	

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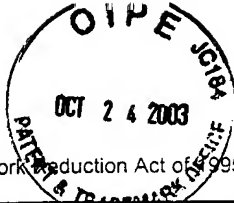
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Sheet 20 of 27

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Application Number	10/330,696
Filing Date	12/23/2002
First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	071949-5602

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		Group Art Unit	Unassigned
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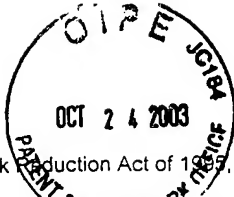
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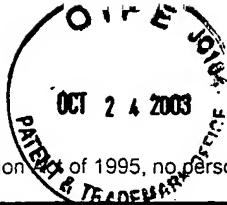
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(use as many sheets as necessary)		Group Art Unit	Unassigned
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Sheet 23 of 27		Attorney Docket Number	071949-5602

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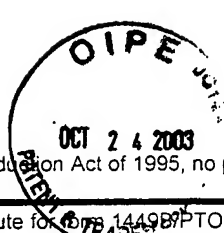
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	C275	Skogseid et al., "Increased serum creatine kinase BB and neuron specific enolase following head injury indicates brain damage," <i>Acta Neurochir (Wein)</i> , 115: 106-111 (1992).	
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	C284	Stockman et al., "Secondary structure and topology of interleukin-1 receptor antagonist protein determined by heteronuclear three-dimensional NMR spectroscopy," <i>Biochemistry</i> 31:5237-5245 (1992).	
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	C286	Suga et al., "Clinical significance of MCP-1 levels in BALF and serum in patients with interstitial lung diseases," <i>Eur. Respir. J.</i> 14:376-382 (1999).	

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		First Named Inventor	Kenneth F. Buechler
		Group Art Unit	Unassigned
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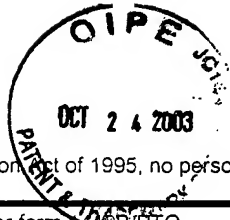
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	C288	Taira et al., "Serum B12 tryptase level as a marker of allergic airway inflammation in asthma," <i>J. Asthma</i> 39:315-22 (2002).	
	C289	Takahashi et al., "Tissue factor in plasma of patients with disseminated intravascular coagulation," <i>Am. J. Hematol.</i> 46:333-337 (1994).	
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		Filing Date	12/23/2002
		First Named Inventor	Kenneth F. Buechler
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Sheet 25 of 27	Attorney Docket Number	071949-5602	

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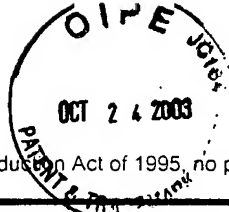
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	C300	Tohgi et al., "Coagulation-fibrinolysis abnormalities in acute and chronic phases of cerebral thrombosis and embolism," <i>Stroke</i> 21: 1663-1667 (1990).	
	C301	Tomoda, H. and Aoki, N., "Plasma soluble P-selectin in acute myocardial infarction: effects of coronary recanalization therapy," <i>Angiology</i> 49:807-813 (1998).	
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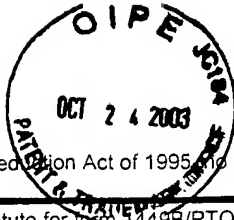
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